UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DAVID SPECTOR, Individually and on Behalf of All Others Similarly Situated,, Plaintiff, L'ORÉAL USA, INC. and VALEANT PHARMACEUTICALS INTERNATIONAL, INC., Defendants.	CASE NO. 1:17-cv-09123-RJS Action Filed: November 21, 2017

L'ORÉAL USA, INC. AND VALEANT PHARMACEUTICALS INTERNATIONAL INC.'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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I. INTRODUCTION AND SUMMARY OF ARGUMENT.

Plaintiff's putative class action claims that three CeraVe sunscreen products – SPF 30 Body Lotion, and SPF 30 Face Lotion, and SPF 50 Body Lotion – do not have the sun protection factor ("SPF") values that are stated on the labels, because Plaintiff allegedly re-tested the products with a different panel of human subjects and got different results. As a matter of law, Plaintiff's claims are preempted, because under FDA rules for sunscreen labeling the SPF value is determined by manufacturer testing with no additional subjects or retesting allowed outside certain defined circumstances, and plaintiffs' state law claims are predicated on the contention that additional subjects or retesting can be used to impose a different SPF value. Plaintiff's attempt under state law to require re-labeling based on subsequent or additional testing of an additional panel or panels of human subjects, and disregard of the original test panel results, would impose a different or additional requirement not identical to the FDA rule.

In addition, Plaintiff's state-law claims are inadequately pleaded or meritless as a matter of law on other grounds. Plaintiff's complaint for breach of warranty fails because the UCC bars recovery unless Plaintiff has given pre-suit notice, either to the manufacturer or the retailer, of a product deficiency so that there is an opportunity to discuss and resolve the issue; he never alleges that he did either. Plaintiff's claim for breach of "implied" contract, and the implied covenant of good faith and fair dealing, fails because Plaintiff does not allege elements of a contract with either L'Oréal or Valeant; he alleges he bought the products from CVS Pharmacy. Plaintiff's claim for "unjust enrichment" likewise fails because he does not allege he dealt directly with Valeant; any benefit he conferred was on CVS Pharmacy, not the original manufacturer. Plaintiff's claim for violation of the New Jersey Consumer Fraud Act fails because he does not adequately plead ascertainable loss: he never states how much less he would have paid if the product had been differently labeled, or even how one could ascertain his loss. Plaintiff's claim for violation of the New Jersey Truth In Consumer Contract Warranty and Notice Act ("TCCWNA") fails because it does not create a private right of action where the underlying law does not.

II. FACTUAL AND REGULATORY BACKGROUND.

A. Sunscreens Are Regulated As An Over-The-Counter Drug; FDA Has Defined The Number Of Test Subjects.

Sunscreens and their labels are regulated by the U.S. Food and Drug Administration as an over-the-counter drug. In 1972, the Commissioner of Food and Drugs appointed an Advisory Review Panel; this work eventually resulted in a 1978 proposed rule for sunscreen labeling. 43 Fed. Reg. 38206-38269 (Aug. 25, 1978). The proposed rule defined which active ingredients could be used as safe and effective, and set out rules that would result in a product being deemed misbranded. *Id.* The 1978 recommendation included a proposal to adopt a term used in Europe, "Sun Protection Factor" or "SPF," and a draft procedure for how to determine it. *Id.* at 38213; 38259-38263. This effort represented a "first attempt to standardize sunscreen testing methods." 52 Fed. Reg. 33598, 33599 (Sep. 4, 1987).

The basic principle behind SPF testing is to expose a panel of human subjects to ultraviolet rays, and measure the average (mean) ratio in the simulated solar energy required to create redness (erythema) on the skin of their back without sunscreen and with the tested product. 21 C.F.R. § 201.327 (2012) (i) (test procedure), esp. at (i)(1) (defining UV source); (i)(3) (test subjects); (i)(4) (application of sunscreen and standard formulation); (i)(5) (UV exposure producing perceptible redness); (i)(6) (calculation and standard errors); *compare* ECF 26 (Am. Compl.) ¶ 31 (stating a different definition of SPF: "The SPF number stands for the approximate measure of time a person who has applied the sunscreen can stay out in the sun without getting burned, compared to the amount of time a person with no protection will get burned in similar conditions."). To help control for variation between laboratories and among human subjects, a separate control formulation with padimate and oxybenzone as active ingredients is tested in parallel, and if the results on this padimate-oxybenzone control sunscreen formula, called the "SPF standard," differ in a defined way from the expected results, this can cause the need for a re-test. 21 C.F.R. § 201.327(i)(2) (recipe for SPF standard formulation); (i)(6) (average measured SPF of standard formulation must fall between 12.87 and 19.73, i.e.,

16.3 +/- 3.43, for test to be valid).

During the rulemaking process, questions were raised about the proposed procedures and statistical methods for determining the validity of the SPF claim. By 1988 there was still no Final Rule, and a public meeting to address questions and comments about the procedure for determining the SPF value was held. *See* 52 Fed. Reg. at 33599 (giving notice of 1988 public meeting and describing purpose).

One key issue in the proposed rule was the number of subjects.[1] The 1972 Advisory Review Panel had recommended groups of twenty subjects but that additional subjects should be added if the standard error exceeded 5% of the mean; by 1978, FDA stated "The agency believes that the number of subjects for a test panel should be fixed before the test and should not be changed." FDA proposed that the number of subjects be a minimum of 20, but that "The panel size shall be fixed in advance and additional subjects shall not be added." 52 Fed. Reg. at 33600.

By 1993, a "tentative final monograph" was issued; in this, the number of subjects remained at 20. 58 Fed. Reg. 28194 (May 12, 1993). In 1999, after re-opening the record several times, *see* 59 Fed Reg. 16042 (Apr. 5, 1994); 61 Fed. Reg. 42398 (Aug. 15, 1996), the FDA issued "a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) sunscreen drug products are generally recognized as safe and effective and not misbranded as part of FDA's ongoing review of OTC drug products." 64 Fed. Reg. 27666 (May 21, 1999). The final rule required a test panel of "not more than 25 subjects with

[1] In addition to the number of test subjects, the FDA rulemaking process has evaluated a number of other elements of the testing, and set detailed rules for each, such as the rejection of the use of natural sunlight in testing in favor of a tightly defined set of parameters for the artificial light source; procedures for selecting the human subjects to ensure adequate testing; details of how to formulate the control sunscreen used to ensure cross-laboratory similarity; criteria for evaluating whether the required degree of skin reddening (erythema) has occurred, including a requirement that different lab technicians apply the sunscreen vs. evaluate for erythema; specifications for the weight, volume, and surface area of the application of the product being tested and the control formulation; and so on. For this motion, the focus is on the use of additional test subjects or panels, and on the conditions under which a test panel's results may be considered invalid so that re-testing is used to determine the SPF value for the label.

the number fixed in advance by the investigator. From this panel, at least 20 subjects must produce valid data for analysis." 64 Fed. Reg. at 27691 (1999 version of 21 C.F.R. § 352.72(g)). In 2007, FDA proposed to reword the rule to provide "A test panel shall consist of 20 to 25 subjects with at least 20 subjects who produce valid data for analysis. Data is valid unless rejected in accordance with [§ 352.70(c)(9)]. If more than 5 subjects are rejected based on [§ 352.70(c)(9)], the panel is disqualified, and a new panel must be created." 72 Fed. Reg. 49070, 49117 (Aug. 27, 2007) (2007 version of 21 C.F.R. § 352.70(c)(7)(i)). For products with an expected SPF of 30 or over, the 2007 proposed rule required 25-30 test subjects, with at least 25 valid results. *Id.* (2007 version of 21 C.F.R. § 352.70(c)(7)(ii)).

A final change to the number of test subjects in the panel took place in 2011. Other countries had adopted standards requiring smaller panels of human subjects, and FDA considered whether it should do the same. So in 2011, the final rule rejected the earlier requirement of a 25-30 person panel. FDA explained that it was making a tradeoff between accuracy and economy, stating that it thought a lower number of subjects would be sufficiently accurate, would minimize the need to include more human subjects (whose skin would be damaged by the testing), and would also harmonize FDA's rule with international standards:

> We agree with the submissions and are lowering the number of test subjects required for SPF testing. . . . We are reducing the number of test subjects in this document because the data we received demonstrate that SPF testing can be conducted with adequate accuracy and precision using as few as 10 test subjects, even when testing high SPF products. The submissions include SPF test results for several sunscreen formulations using panels of 20 to 25 test subjects. We randomly selected 10 subjects within each of these panels to determine if using fewer subjects significantly decreased test accuracy and precision. For each of these panels, the mean SPF value and standard error calculated from a randomly selected subset of 10 subjects were not significantly different from those calculated from all 20 to 25 subjects in the panel. Therefore, these data indicate that using as few as 10 test subjects will not compromise SPF test accuracy or precision. Consequently, fewer test sites and subsites need to be tested, and fewer test results need to be rejected, thereby decreasing the number of test subjects needed. Our revised SPF test subject number requirement is similar to the COLIPA [European] SPF test requirement. The only significant difference related to test subject number is that we are not including a statistical requirement or allowing individual subjects to be added incrementally to a test panel as

allowed under the COLIPA SPF test.

76 Fed. Reg. 35620, 35646-47 (June 17, 2011). Thus, the final rule stated, with respect to number of test subjects, "A test panel should include enough subjects to produce a minimum of 10 valid test results. A maximum of three subjects may be rejected from this panel based on paragraph (i)(5)(v) of this section." 76 Fed. Reg. at 35663 (21 C.F.R. § 201.327(i)(3)(i)). As the comments indicate, unlike European standards, the FDA rule does not to allow subjects to be added incrementally after the initial test panel is constituted and tested.

B. Allegations About Testing Of The CeraVe Sunscreens.

The complaint makes the following non-conclusory allegations[2] about testing of CeraVe sunscreens products ("Products"), which for purposes of this motion are taken as true:

First, Plaintiff alleges that Defendants did testing prior to the Products being offered for sale. ECF 26 (Am. Compl.) ¶ 44. Plaintiff makes no further allegations about the testing done by Defendants.[3] He does not claim that Defendants' testing did not follow the correct FDA

[2] A motion to dismiss under Rule 12(b)(6) tests whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When deciding a Rule 12(b)(6) motion, the court must accept the facts pleaded in the complaint as true, and construe them in the light most favorable to the plaintiff. *Gregory v. Daly*, 243 F.3d 687, 691 (2d Cir. 2001), as amended (Apr. 20, 2001). After accepting all non-conclusory allegations as true and drawing all reasonable inferences in favor of the plaintiff, the court must determine whether the complaint alleges a plausible claim to relief. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . . The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *See Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556).

[3] Paragraphs 43 and 44 allege, without more, that Defendants "should have been aware" that the products did not have the SPF ratings they claimed. This allegation is not supported by any specific or plausible allegations about the Defendants' testing, and in the context of the complaint, appears to be based solely on the fact that Plaintiff's lab, and Consumer Reports, reported a different result. If Plaintiff contended that the result of Defendant's SPF testing was lower than the stated SPF value, Plaintiff would and could have alleged that Defendant actually knew, not merely "should have" known, that the SPF value was incorrect.

protocol (which he refers to when describing his own testing, *see id.* at ¶¶ 5 and 37), or that Defendants did not correctly report the result of the SPF testing on the product label as required by 21 C.F.R. § 201.327.

Second, he alleges that Consumer Reports magazine tested the products and stated that the products had SPFs "Below 50% labeled SPF." ECF 26 (Am. Compl.) at ¶¶ 35-36. Plaintiff does not claim that Consumer Reports tested according to the correct FDA protocol.

Third, Plaintiff alleges that he conducted "his own independent testing . . . utilizing the methodology for SPF testing mandated by the FDA." *Id.* at ¶ 37. He states that his testing followed "all FDA testing methods embodied in FDA Final Rule . . . including 21 CFR 201.327." *Id.* at ¶ 38.

Fourth, Plaintiff states the results of his testing. Unfortunately, the allegations are inconsistent, reporting different results for the same alleged tests:

First Amended Complaint at ¶ 5	**First Amended Complaint at ¶ 40**
"In the case of the Body Lotion SPF 50, Plaintiff's testing showed an SPF average value of 17.4."	"Specifically, the results of the independent testing indicated an average value of . . . 13.7 for the Body SPF 50."
"In the case of the Face Lotion SPF 30, Plaintiff's testing showed an SPF average of 15."	"Specifically, the results of the independent testing indicated an average value of 13.2 for the Face SPF 30 . . . ."
"In the case of the Body Lotion SPF 30, Plaintiff's testing showed an SPF average of 16."	"Specifically, the results of the independent testing indicated an average value of . . . 10.4 for the Body SPF 30 . . . ."

C. Plaintiff Purchases Sunscreen, Then Sues.

Plaintiff alleges that he purchased both the CeraVe SPF 30 Body Lotion and CeraVe SPF 30 Face Lotion products at a CVS Pharmacy in Ocean City, New Jersey, on August 6, 2017, and the SPF 50 product at a CVS Pharmacy in Voorhees, New Jersey sometime around 2016. ECF 26 (Am. Compl.) ¶ 18. He claims he purchased these products "several times during the statute of limitations as well." *Id.* He does not allege whether the products he bought were sold to CVS by Valeant (which owned the CeraVe product line prior to March 3, 2017) or by L'Oréal (which

owned the product line after March 4, 2017). *Id.* ¶ 27.

Plaintiff does not allege that he gave any pre-lawsuit notice of his dissatisfaction with his purchase. He instead alleges that "Defendants were on notice of their breaches of express warranty by virtue of the *Consumer Reports* article referenced herein." *Id.* ¶ 89.

On behalf of a putative class of nationwide consumers, and a putative subclass of New Jersey consumers, Plaintiff alleges claims for (1) Breach of Warranty; (2) Breach of Implied Contract and Violation of the Implied Covenant of Good Faith and Fair Dealing; and (3) Disgorgement/ Restitution. ECF 26 (Am. Compl.) ¶¶ 81-106. On behalf of the New Jersey subclass alone, Plaintiff brings claims for violations of (4) the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq.*; and (5) the New Jersey Truth in Consumer Contract, Warranty and Notice Act, N.J.S.A. 56:12-14 *et seq.* ECF 26 (Am. Compl.) ¶¶ 107-22.

III. ARGUMENT.

A. All of Plaintiff's State-Law Claims Are Preempted By Federal Sunscreen Testing and Labeling Regulations.

1. Plaintiff's Claims Based on Re-Testing Would Impose An Additional or Different Requirement From The FDA Regulation That Permits No Additional Test Subjects, And Invalidates An Initial Panel's Test Results Only In Limited Circumstances Not Alleged Here.

The Food, Drug & Cosmetic Act expressly preempts any state requirement concerning drug labeling that is "different from or in addition to, or that is otherwise not identical with, a requirement" established by FDA regulations. 21 U.S.C. § 379r(a); *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 374-75 (S.D.N.Y. 2014) ("The standard . . . is whether state law diverges from federal law *at all*.") (emphasis in original); *In re PepsiCo, Inc,. Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008) ("Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements."). This rule applies to sunscreen labeling, which is regulated as an over-the-counter drug by the FDA. *Eckler v. Neutrogena Corp.*, 189 Cal. Rptr. 3d 339, 344 (Cal. Ct. App. 2015); *Gisvold v. Merck*

& Co., Inc., 62 F. Supp. 3d 1198 (S.D. Cal. 2014). Thus, for example, if FDA has considered a rule but declined to adopt it for an FDA-regulated over-the-counter drug, a state law claim based on the rule that was not adopted is preempted, because it is not "identical" to the FDA rule. *Bowling*, 65 F. Supp. 3d at 375; *see also Bimont v. Unilever United States, Inc.*, No. 14-CV-7749 (JPO), 2015 WL 5256988 (S.D.N.Y. Sept. 9, 2015) ("State claims are preempted, then, if they (1) impose any non-identical requirement on conduct that could be regulated by the FDA; (2) impose any non-identical requirement on conduct whose subject matter has been regulated by the FDA; or (3) impose any conflicting requirement on conduct that has been regulated by the FDA.") (citations omitted).[4]

The parties agree that FDA has adopted a rule governing SPF values on sunscreen labels. The critical legal question on this motion is whether plaintiff seeks to impose liability on grounds that are not identical to the FDA rule. Plaintiff claims not to be: it asserts that its state law claims "do not seek to impose any additional or different obligations beyond those already required by" the FDA regulations, and that its claims are "parallel state claims alleging affirmative violations of FDA regulations . . ." ECF 26 (Am. Compl.) ¶ 57-58.

But a close examination of the FDA regulation here, and the allegations on which plaintiff seeks to impose liability under state law, shows otherwise. Plaintiff seeks re-labeling based on re-testing: without ever alleging any flaw that would invalidate Valeant and L'Oréal's testing, he alleges that his lab got a lower result when it re-tested. ECF 26 (Am. Compl.) ¶ 39-40. This is contrary and non-identical to the FDA testing methodology.

The FDA was clear, throughout the 1978, 1993, 1999, 2007, and 2011 rulemakings that the number of subjects that will be tested in order to establish the SPF value for the product is to

[4] Courts consistently reject the argument that the FDA's more generalized prohibition on "misbranding" provides a basis for imposing false labeling liability on a basis not identical to the federal regulations for over-the-counter drugs. *See, e.g.*, *Bowling*, 65 F. Supp. 3d at 374-75; *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1282-83 (C.D. Cal. 2008).

be determined in advance, and that using results from additional test subjects after the initial panel's results are known is an invalid approach. 76 Fed. Reg. at 35646-47 ("we are not . . . allowing individual subjects to be added incrementally to a test panel as allowed under the COLIPA SPF test."); 64 Fed. Reg. at 27691 (1999 final rule, 21 C.F.R. § 352.72, requiring test panel of "not more than 25 subjects with the number fixed in advance by the investigator. From this panel, at least 20 subjects must produce valid data for analysis."); 52 Fed. Reg. at 33600 (1978: rejecting original 1972 Advisory Review Panel proposal to add additional subjects if standard error exceeded 5% of the mean: "The agency believes that the number of subjects for a test panel should be fixed before the test and should not be changed."); *id.* ("The panel size shall be fixed in advance and additional subjects shall not be added.").

The FDA's final 2011 rule, stating that the principal display panel shall state "SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section]," 21 C.F.R. § 201.327(a)(1)(i) and (ii), and specifying that the test procedure includes "*Number of subjects.* A test panel should include enough subjects to produce a minimum of 10 valid test results. A maximum of three subjects may be rejected from this panel based on paragraph (i)(5)(v) of this section," should thus be interpreted, as a matter of law, to mean that the SPF result stated on the front panel must be from the average (mean) result of the subjects in the panel, not reevaluated based on testing of additional subjects or panels. By claiming that the SPF value can be determined/revised by re-testing or additional testing, e.g., that the average of the first ten people tested by Valeant can be ignored or disregarded based on results from an additional ten people (or more), Plaintiff is adding additional subjects to the methodology for determining what Plaintiff claims is the "actual SPF" or the "true SPF." ECF 26 (Am. Compl.) ¶ 40, 43. This diverges from the FDA methodology, which prohibits determining an SPF value using additional subjects, and plaintiff's state law claim is thus preempted.

FDA does allow for disregarding the results of the initial panel and re-testing, but only in two circumstances. First, if there are more than three subjects are rejected from the test panel, on the grounds specified in 201.327(i)(5)(v), the test panel results are invalidated, and a new panel

would need to be constituted, even if 10 valid test results were otherwise obtained. 21 C.F.R. § 201.327(i)(3)(i). In 201.327(i)(5)(v), FDA gave the four exclusive reasons why a subject's data would be rejected:

(1) **No redness anywhere.** "[I]f erythema is not present on either the unprotected or protected test sites";

(2) **Redness everywhere.** "[I]f erythema is present at all subsites";

(3) **Illogical pattern of redness**, e.g., redness at lower radiation dose but not higher. "[T]he responses are inconsistent with the series of UV doses administered;"

(4) **Non-complaint subject.** "[T]he subject was noncompliant (e.g., the subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined)."

Second, FDA requires re-testing if the padimate-oxybenzone "SPF standard" formulation, prepared under the recipe in 201.327(i)(2), produces a result outside the standard deviation range of the expected SPF value for the padimate-oxybenzone formulation: "In order for the SPF determination of a test product to be considered valid, the SPF value of the SPF standard [i.e., the padimate-oxybenzone formulation] should fall within the standard deviation range of the expected SPF [for the padimate-oxybenzone formulation] (i.e., 16.3 +/- 3.43)." 21 C.F.R. § 201.327(i)(6). Plaintiff's proposed state law claims would create a new and different reason to disregard the results of the original panel. By using subsequent test data to undermine or contradict the validity of the SPF value reported on the label after Valeant's initial testing, Plaintiff's state law claims would treat the initial result as invalid if a fact-finder concluded that subsequent testing was a more persuasive measure of the SPF value, and would permit an SPF value that disregarded the results of subjects in the initial panel for reasons other than the four specified grounds in 21 C.F.R. 201.327(i)(5)(v). Because FDA specified the conditions under which the test panel's results would be considered "valid" (or invalid), and did not include subsequent testing as a valid basis for rejecting the results of the panel – indeed deliberately chose not to permit additional subjects to be used after the panel was constituted – plaintiff's state law claims would impose liability based on a rule that is non-identical.

FDA recognized that it was creating a rule that would not be perfect, but adopted it because it thought the results would have "adequate accuracy" to provide useful information to consumers. The SPF value is not a true or false question: it is an average of test results taken from a panel of human subjects tested according to a particular methodology. The test procedure is known to generate very different results even if the exact same recipe is used for sunscreen. A test panel where the results of the "SPF standard" padimate-oxybenzone formulation are 12.9 is just as valid as one where the results of using the exact same formulation, prepared in the exact same way, are 19.7. *See* 201.327(i)(6). Intentionally giving sunburns to more human subjects might lead to a more accurate estimate of how the sunscreen will work on the human population more generally, but only at the cost of damaging more test subjects' skin. FDA expressly decided against a rule that would take the average result of 25 or more human subjects; it decided that there wasn't a significant enough difference in average test outcomes to overcome the policy benefits of reducing harmful human subject testing and aligning the FDA requirement with European standards. 76. Fed. Reg. at 35646-47. There is no such thing as a "true SPF" or "actual SPF," as plaintiff claims. There is only the average result of a test, and the test results will not always be the same. If the test is properly conducted, the product is properly sold with that test result on its label. The premise of plaintiff's lawsuit, that a different test result means false labeling, is fundamentally inconsistent with the FDA rule, which calls only for the label to report the average result of a test procedure on less than a dozen human subjects.

A fact-finder thus cannot be asked, in adjudicating a state law claim, whether it finds plaintiff's subsequent re-testing to be more persuasive, or whether it "more likely than not" reflects the "true SPF" or "actual SPF" value of the products, because this standard differs from the FDA grounds for determining the validity of the defendant's test results. *Bowling*, 65 F. Supp. 3d at 374-75 ("The standard . . . is whether state law diverges from federal law *at all*."). This is not a mere "evidentiary" issue; it goes to the core of whether plaintiff's claims are preempted. If at summary judgment or trial, a factfinder cannot rule in plaintiff's favor based on proof that plaintiff obtained a result of 13.7, as plaintiff alleges he did, because plaintiff did not

also prove that Valeant's testing showing a result of 50 had more than three invalid test subjects, or that the padimate-oxybenzone result was outside the standard deviation of 16.3 +/- 3.43, then plaintiff's claim fails to state a claim today: plaintiff does not plead that Valeant's testing was invalid for any reason set forth in the FDA rule. If at summary judgment or trial, a factfinder cannot determine a different SPF value than the mean result of Valeant's panel, because FDA does not allow additional test subjects to be used in coming up with the mean result to be reported on the label, then plaintiff's claim fails at the pleading stage: plaintiff does not allege that the panel results were not SPF 30 or SFP 50; he alleges only that additional subjects had an average that was lower. Absent an allegation that the initial result was invalid, Valeant and L'Oréal are permitted (indeed, required) to put the SPF value on the label, and a state-law rule that prohibits it from doing so, on the ground that subsequent re-testing calls the result into question because the subsequent re-testing had a different outcome, is preempted.

Plaintiff's claim cannot rest on the results of tests conducted by Consumer Reports for an additional reason. He does not allege that Consumer Reports complied with 21 C.F.R. § 201.327(i)'s protocols. Because Consumer Reports' testing does not necessarily track federal testing rules, claims for false advertising or labeling based on Consumer Reports testing, where the FDA has established the testing regime, are preempted. *In re Whole Foods Mkt., Inc.*, 163 F. Supp. 3d 385, 392–93 (W.D. Tex. 2016) (considering a false advertising claim against a yogurt manufacturer based on Consumer Reports tests of that yogurt's sugar content; granting motion to dismiss for failure to allege compliance with FDA testing procedures) (citing cases); *cf. Carroll v. S.C. Johnsons & Son, Inc.*, No. 17-cv-5828, (Mar. 29, 2018), ECF No. 53 (Mayhew Decl. Exh. A) (allegations about Consumer Reports were irrelevant not alleged to follow FDA methodology). Because Plaintiff did not allege Consumer Reports complied with FDA required procedure when conducting its testing, Consumer Reports opinions on the Product's efficacy are irrelevant from a labeling perspective. The Consumer Reports tests cannot be the basis of Plaintiff's false labeling claim.

2. *Dayan* and *Carroll* Are Unpersuasive Because The Argument Made Here Was Not Made, And So Was Not Discussed Or Ruled On.

During the pre-motion conference, Plaintiffs cited two cases as ruling that claims about SPF values on sunscreen are not preempted: *Dayan v. Swiss-American Prods., Inc.*, 15-cv-6895 (DLI)(VMS), 2017 WL 1214485 (E.D.N.Y. Mar. 31, 2017) and *Carroll v. S.C. Johnsons & Son, Inc.* (Mayhew Decl. Exh. A). The Court should not find those cases persuasive, because neither case directly addressed the arguments made here.

Instead, in *Dayan* the magistrate judge recommended no express preemption because it did not understand plaintiffs to be arguing anything other than "that the product conform precisely to rules established by the FDCA; namely, that the product display an accurate SPF value." *Dayan v. Swiss-American Prods., Inc.*, 15-cv-06895 (DLI) (VMS), (E.D.N.Y. Jan. 3, 2017) (Report and Recommendation), ECF No. 23 (attached as Exh. B to Mayhew Decl.) ("Dayan R&R"). Defendant's argument for express preemption appears to have been the weak argument that the state law claim was inconsistent because of a request for injunctive relief requesting, somewhat vaguely, improved quality control and product labeling practices. *See* Mayhew Decl. Exhs. C, D, E, F, G (briefing). The district court, in adopting the Dayan R&R, went no further with the analysis of express preemption than the magistrate judge. *See Dayan*, 2017 WL 1214485, at *3. None of the arguments made in section A.1 above were addressed.

To the extent that defendant in *Dayan* argued that its own prior testing had any significance at the motion to dismiss stage, defendant's argument was that its prior tests showing an SPF value of 45 meant that plaintiff's test result was "implausible and thus insufficient under the standard enunciated in *Iqbal*." *Dayan R&R*, at p. 27. This claim was easily disposed of using the standard for motions to dismiss, i.e., that plausibility does not involve weighing the evidence. *Id.* at 27-28. The *Dayan* defendant's lack of success with an ill-founded plausibility argument using evidence outside the complaint will not meaningfully assist the Court with deciding the preemption argument made here. While both cases facially involve a defendant making a motion to dismiss and pointing out a conflict between the defendant's testing and the

plaintiff's, and both cases brief preemption, the *Dayan* defendant did not make the same argument now made here, and the Court's ruling on the *Dayan* defendant's motion therefore does not provide persuasive reasons or analysis that can assist the Court in resolving the issues presented on this motion. Valeant and L'Oréal's argument is not that plaintiff's test results are implausible – with human variation and statistical probabilities for a ten person sample size, they might well be plausible[5] – but instead that state law is preempted if it permits disregard of the initial test panel results on grounds other than (1) disqualification of three panelists under the four grounds in (i)(5)(v), or (2) unacceptably high deviation from the expected result for the padimate-oxybenzone SPF standard. Plaintiff's failure to plead proper grounds under the FDA rule for invalidating the manufacturer's testing means the claim is preempted.

Carroll is even simpler. There, the defendant seems to have argued only that the complaint was based on the Consumer Reports testing and therefore preempted because of lack of indication that the Consumer Reports testing followed FDA methods. Defendant did not argue that finding state law liability based on plaintiff's separate allegation about independent testing would impose a different or additional requirement. The cursory discussion of preemption in *Carroll* is unpersuasive on the argument made here, because it does not address it.

B. Plaintiff's State-Law Claims Do Not State a Claim For Relief As a Matter of State Law.

Independent of the federal preemption issue, each of Plaintiff's state-law claims fail as a matter of state law. "A federal court sitting in diversity must apply the choice of law rules of the forum state, in this case New York." *Lazard Freres & Co. v. Protective Life Ins. Co.*, 108 F.3d 1531, 1538 (2d Cir. 1997). "In contract cases, such as where a breach of warranty is alleged, New York courts apply a 'center of gravity' or 'grouping of contracts' approach"; most

[5] For example, the FDA record for the rulemaking included testing provided by Procter & Gamble showing that duplicate testing of the same product by different labs and panels of 20-25 subjects led to a wide range of SPF results; for an "SPF 100" product, results ranged from 37 to 75. *See* Mayhew Decl. Exh. H.

important is the place of contracting and performance. *In re Frito-Lay N. Am., Inc. All Nat. Litig.*, No. 12-MD-2413 RRM RLM, 2013 WL 4647512, at *19 (E.D.N.Y. Aug. 29, 2013) (citing *Lazard*, 108 F.3d at 1539). Plaintiff alleges he purchased the SPF 30 products in New Jersey, ECF 26 (Am. Compl.) ¶ 18, so New Jersey is the place of contracting and performance and its law applies to Mr. Spector's common law claims and New Jersey statutory claims.

1. *The First Claim, for Breach of Warranty, Is Barred By UCC 2-607.*

Plaintiff's first claim is for breach of warranty. Under the UCC, to recover under a theory of breach of warranty, "*the buyer must* within a reasonable time after he discovers or should have discovered any breach *notify the seller of breach or be barred from any remedy*." *See* N.J. Stat. § 12A:2-607(3)(a) (emphasis added). Plaintiff does not allege that he notified anyone, let alone Valeant or L'Oréal, that he was unsatisfied with the products he bought. Plaintiff argues alternatively (1) he was not required to give notice to the seller or anyone else, because he is a remote buyer suing a manufacturer, (2) the notice requirement was satisfied by filing suit, or (3) the notice requirement was satisfied by an article in Consumer Reports magazine. Each argument fails.

In *Duall Building Restoration, Inc. v. 1143 East Jersey Avenue, Associates, Inc.*, 279 N.J. Super. 346, 652 A.2d 1225356–57 (N.J. Super. Ct. App. Div. 1995), the New Jersey appellate court addressed "what, if anything, a remote buyer must do to satisfy the notice requirement of N.J.S.A. 12A:[2]-607(3)(a)." The Court in that case reconciled the clear requirements of the rule – that the buyer must "notify the seller of breach" – with the difficulties of notifying a remote manufacturer. Analyzing the question as one of statutory interpretation, the court held:

> In accordance with this definition, we hold that a remote buyer that has suffered economic loss as the result of a manufacturer's breach of its implied warranty of fitness for a particular purpose can "notify the seller of breach" within the meaning of N.J.S.A. 12A:2-607(3)(a) without communicating directly with the seller. . . . A buyer that informs its immediate seller within a reasonable time that there is a problem with an identified product "has taken such steps as may be reasonably required . . . to inform" a manufacturer that is not its immediate seller about the breach.

Duall, 279 N.J. Super. at 357 (citing cases).[6] The court held that this interpretation satisfied the statutory purposes of 2-607(3)(a), because of the likelihood that the direct seller would give notice up the supply chain. *Id.* at 357-58; *see also Cipollone v. Liggett Grp., Inc.*, 683 F. Supp. 1487, 1498 (D.N.J. 1988) ("At the least, New Jersey would follow other courts who have ruled that § 2-607(3)(a) requires a buyer to give notice only to his immediate seller.").[7]

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[6] This interpretation reconciles New Jersey law with other states that hold that notice to at least the direct seller is required. *Duall*, 279 N.J. Super. at 357 (citing *Church of the Nativity of Our Lord v. WatPro, Inc.*, 491 N.W.2d 1, 6 (Minn. 1992) (notice requirement satisfied by notice to immediate seller); *Seaside Resorts, Inc. v. Club Car, Inc.*, 308 S.C. 47, 59-60 (S.C. Ct. App. 1992) (UCC notice provision required retail buyer to notify seller who tendered goods to him, but not also wholesalers or others further up chain of commerce); *see also In re Air Bag Prods. Liab. Litig.*, 7 F. Supp. 2d 792, 804 n.18 (E.D. La. 1998) (even though the Texas Supreme Court had expressly reserved judgment on whether notice to an immediate seller satisfies the requirements of § 2–607(3), recovery was barred where plaintiffs made no attempt to notify either the manufacturer or the immediate seller); *Doll v. Ford Motor Co.*, 814 F. Supp. 2d 526 (D. Md. 2011) (under Maryland, South Carolina, and Pennsylvania law, 2-607(3)(a) barred buyer from claim against manufacturer where he failed to give notice to anyone, including his immediate seller); *Brooking Mun. Utilities, Inc. v. Amoco Chem. Co.*, 103 F. Supp. 2d 1169 (D. S.D. 2000) (under South Dakota law, 2-607(3)(a) barred claim where no notice was given to direct seller or manufacturer); *Sullivan v. Young Bros. & Co., Inc.*, 91 F.3d 242 (1st Cir. 1996) (under Maine law, 2-607(3)(a), if notice of breach to seller of product alone is insufficient, fact finder could infer that notice to manufacturer's exclusive representative in state was sufficient notice to manufacturer on agency theory); *Palmer v. A.H. Robins Co., Inc.*, 684 P.2d 187 (Colo. 1984) (notice to immediate seller was given and was sufficient); *Hobbs v. Gen. Motors Corp.*, 134 F. Supp. 2d 1277 (M.D. Ala. 2001) (under Alabama law, 2-607(3)(a) required notice provided directly to manufacturer or provided to them by direct seller from the buyer); *Goldstein v. G.D. Searle & Co.*, 62 Ill. App. 3d 344, 378 N.E.2d 1083, 1086 (Ill. App. 1978) (remote manufacturer may raise lack of notice to the immediate seller as a defense); *cf. also McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 706 (5th Cir. 2014) (notice required to both the remote manufacturer and the immediate seller).

[7] On this point, *Cipollone* noted that in *Santor v. A & M Karagheusian, Inc.*, 44 N.J. 52, 67–68, 207 A.2d 305 (1965) (abrogated on other grounds by *Alloway v. Gen. Marine Indus., L.P.*, 149 N.J. 620, 643 (1997), the New Jersey Supreme Court had held, under the previously applicable Uniform Sale of Goods law, that notice of defective merchandise need not be provided to a manufacturer who was not the immediate seller of the product. *Cipollone*, 683 F. Supp. at 1498. *Santor* did not conclusively address the issue in its cursory discussion, because in that case, "in any event, plaintiff gave prompt notice to his immediate seller." 44 N.J. at 68. As *Duall* notes, the New Jersey Supreme Court has more recently reserved judgment on this precise issue after the passage of the UCC. *See Duall*, 279 N.J. Super. at 356-57 ("Therefore, although the Supreme Court in *Spring Motors Distributors, Inc.*, *id.*, 98 N.J. at 589, 489 A. 2d

(footnote continued)

In *Strzakowlski v. General Motors Corp.*, No. CIV.A. 04-4740, 2005 WL 2001912 (D.N.J. Aug. 16, 2005), the federal district court noted that *Cipollone* had predicted that no notice would be required against a remote manufacturer, and the alternative holding that the New Jersey Supreme Court would require notice only to his immediate seller. *Id.* at *3. Without further analysis, the Court stated that it was following the first *Cipollone* statement that no notice must be given to a manufacturer, but thereby extended *Cipollone* even where there was no notice to the immediate seller. *Id.* *Strzakowlski* did not analyze or mention *Duall*. Other district court decisions have followed *Strzakowlski* on this point without further analysis. *See, e.g., Coyle v. Hornell Brewing Co.*, No. CIV. 08-02797 (JBS), 2010 WL 2539386 (D.N.J. June 15, 2010). Meanwhile, the New Jersey district court has also sometimes reached the opposite result. *See, e.g., Kury v. Abbott Laboratories, Inc.*, No. CIV.A. 11-803 FLW, 2012 WL 124026, at *1,*7 (D.N.J. Jan. 17, 2012) (dismissing express warranty claim against infant formula manufacturer who sold brand through "grocery stores and pharmacies" as barred by N.J.S.A. 12A:2-607(3)(a) where "Plaintiff has failed to plead that she provided the pre-litigation notice of breach.").

Rather than following the unreasoned decision in *Strzakowlski* as authoritative, this Court should predict what the New Jersey Supreme Court would do. *Travelers Ins. Co. v. 633 Third Assocs.*, 14 F.3d 114, 119 (2d Cir. 1994) ("Where the substantive [state law] is uncertain or ambiguous, the job of the federal courts is carefully to predict how the highest court of the forum state would resolve the uncertainty or ambiguity."). The *Duall* decision carries special weight in this analysis:

Although we are not strictly bound by state intermediate appellate courts, rulings

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660, expressly refrained from deciding what, if anything, a remote buyer must do to satisfy the notice requirement of [2-607(3)(a)], we must decide that issue in this case."); *see Spring Motors Distribs., Inc. v. Ford Motor Co.*, 98 N.J. 555, 570-71(1985) ("In addition to privity, the [UCC] retains two other requirements that may pose considerable obstacles to a buyer. The first requirement is that of notice to a seller of a breach of warranty, *N.J.S.A.* 12A:2-607(3) . . . . Strict liability . . . circumvents the technical requirements of the U.C.C. with respect to privity, notice, and limitation of damages.").

> from such courts are a basis for "ascertaining state law which is not to be disregarded by a federal court unless it is convinced by other persuasive data that the highest court of the state would decide otherwise."

DiBella v. Hopkins, 403 F.3d 102, 112 (2d Cir. 2005); *id.* at 112-113 (indicating that even dicta of the Appellate Division are helpful indicators of state law, and "it would be inappropriate for a federal court to disregard these cases based solely on the lack of authoritative support for the assertions they contain"). Decisions of other jurisdictions, such as those cited in footnote 6 above, may also be considered persuasive data as to how the New Jersey Supreme Court would rule. *DiBella*, 403 F.3d at 112. The language of the statute – which clearly states that a buyer must give notice to the seller or be barred – is unambiguous in requiring the buyer to notify a seller; while it could be read to require notice only to the immediate seller rather than the defendant manufacturer, it cannot fairly be read to require no notice to any seller in the chain. N.J.S.A. 12A:2-607(3)(a); *Travelers*, 14 F.3d at 112 (requiring analysis of the statutory language in predicting how the state high court would rule). *Strzakowlski* analyzed none of these sources, and is thus unpersuasive as a prediction of New Jersey law, and the cases that invoke *Strzakowlski* with no further analysis do not make it more persuasive by repeating it.

Strzakowlski departs from New Jersey law on a second issue: whether there must be pre-litigation notice, or whether the complaint itself can satisfy the requirement of notice (on the theory that a complaint, like a pre-litigation notice, can lead to settlement talks). Section 2-607(3)(a) requires pre-litigation notice. As the federal district court explained in *Joc, Inc. v. Exxonmobil Oil Corp.*, No. CIV 08-5344 (FSH), 2010 WL 1380750, at *4 (D.N.J. Apr. 1, 2010):

> [P]roviding notice pursuant to this regulation is a condition precedent to filing any suit for breach of contract under Article 2 of the U.C.C. or its state counterparts. *See Caparelli v. Rolling Greens, Inc.*, 39 N.J. 585, 593, 190 A.2d 369 (N.J. 1963) (observing that with the advent of the Uniform Sale of Goods Laws, "notice became an 'absolute condition' of an action for breach of warranty" for the sale of chattel); *Buff v. Giglio*, 124 N.J. Super. 94, 97, 304 A.2d 771 (N.J. Super. A.D. 1973) (explaining that while rejection of the goods is not a prerequisite to an action by the buyer, notification to the seller is).

Id. at *4; *Hammer v. Vital Pharm., Inc., No. CIV.A.-11-4124*, 2012 WL 1018842, at *10 (D.N.J.

Mar. 26, 2012) (filing of a lawsuit does not constitute notice of breach for purposes of UCC notice); *Luppino v. Mercedes-Benz USA, LLC*, No. CIV. 09-5582 DMC JAD, 2011 WL 2470625, at *3 (D.N.J. June 20, 2011) ("At no time has any court in this [New Jersey federal] district or in the state of New Jersey found that a buyer is not required to provide a direct seller with pre-suit notice in an action for express breach of warranty.").[8] The notification requirement helps promote informal resolution of claims without litigation. *Schmidt v. Ford Motor Co.*, 972 F. Supp. 2d 712, 718 (E.D. Pa. 2013) (federal diversity action applying N.J.S.A. 12A:2-607(3)(a)) ("[T]he purpose of notification under § 2607(c) is to allow the seller an opportunity to resolve the dispute regarding an alleged breach before the buyer initiates a lawsuit." (citation omitted)); *Cardinal Health 301, Inc. v. Tyco Elecs. Corp.*, 169 Cal. App. 4th 116, 135 (2008) (describing why pre-litigation notice does not satisfy policies of UCC § 2-607).

Plaintiff does not allege that he provided any pre-suit notice.[9] He instead asserts only that "Defendants were on notice of their breaches of warranty by virtue of the *Consumer Reports* article referenced herein." ECF 26 (Am. Compl.) ¶ 89. This allegation does not satisfy the requirement. The statute requires the buyer – Mr. Spector – to give notice. *See In re Clorox Consumer Litig.*, No. 12-00280 SC, 2013 WL 3967334, at *5 (N.D. Cal. July 31, 2013) ("[N.J. Stat. § 12A:2–607(3)(a)] specifically contemplates notice by the 'buyer,' in this case the New

[8] The citation in these cases to New Jersey appellate precedent makes them a more persuasive prediction of New Jersey law than *Strzakowlski*, which followed *Bednarski v. Hideout Homes & Realty, Inc.*, 709 F. Supp. 90, 92-95 (M.D. Pa. 1988). *Bednarski* itself acknowledged that it was predicting, as a matter of Pennsylvania law, that the Pennsylvania Supreme Court would adopt the minority position on this issue, and that the majority of states hold that the notice must be pre-suit. The Illinois Supreme Court, for example, has held that *Bednarski* should be followed only in cases involving consumer buyers who suffered personal injuries. *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584 (Ill. 1996).

[9] Counsel for Plaintiff is aware of the requirement of pre-suit notification, as they alleged such notifications in recently-filed lawsuits challenging sunscreen labels in other jurisdictions. *See Curran v. Bayer Healthcare LLC and Merck & Co., Inc.*, 1:17-cv-07930, Complaint (ECF No. 1) ¶ 97, (N.D. Ill. 2017); *Carroll et al. v. S.C. Johnson & Son, Inc. and VMG Partners, LLC*, 1:17-cv-05828, Complaint (ECF No. 1) ¶ 90, (N.D. Ill. 2017).

Jersey Plaintiff."); *Luppino v. Mercedes-Benz USA, LLC*, No. CIV. 09-5582 DMC JAD, 2011 WL 2470625, at *3 (D.N.J. June 20, 2011). As Judge Learned Hand wrote in an oft-quoted opinion, "The notice 'of the breach' required is not of the facts, which the seller presumably knows quite as well as, if not better than, the buyer, but of buyer's claim that they constitute a breach. The purpose of the notice is to advise the seller that he must meet a claim for damages, as to which, rightly or wrongly, the law requires that he shall have early warning." *See American Mfg. Co. v. U.S. Shipping Bd. Emergency Fleet Corp.*, 7 F.2d 565, 566 (2d Cir. 1925). Mr. Spector's failure to allege he gave anyone notice, including Valeant, L'Oréal, or CVS Pharmacy, bars his claim.

2. *The Breach of Implied Covenant of Good Faith and Fair Dealing Claim Should Be Dismissed Because Plaintiff Pleads No Breach of an Implied, Rather Than Express, Term.*

Plaintiffs' second claim for relief, for "breach of implied contract and violation of the implied covenant of good faith and fair dealing," fails for lack of adequate allegations to show a contract. "The New Jersey Supreme Court has made clear that, '[i]n the absence of a contract, there can be no breach of an implied covenant of good faith and fair dealing.'" *Martucci v. Procter & Gamble, Inc.*, No. CV 15-4434 (JLL), 2015 WL 6739116, at *3 (D.N.J. Nov. 4, 2015) (quoting *Wade v. Kessler Inst.*, 172 N.J. 327, 345 (2002) (citation omitted)); *Cumberland Farms, Inc. v. New Jersey Dep't of Envtl. Prot.*, 447 N.J. Super. 423, 443 (N.J. Super. Ct. App. Div. 2016); *Chee Li v. BMW of N. Am., LLC*, No. A-0453-15T3, 2017 WL 2625965, at *8 (N.J. Super. Ct. App. Div. 2017). Plaintiff alleges that a contract was formed "by operation of law." ECF 26 (Am. Compl.) at ¶ 96. No further facts are pleaded, and the claim is insufficient as a matter of law. An "implied contract" under New Jersey law requires some "unequivocal assent by both parties before a contract will be implied from the parties' statements or conduct." *Dicuio v. Brother Int'l Corp.*, No. CIV.A. 11-1447 FLW, 2012 WL 3278917, at *14 (D.N.J. Aug. 9, 2012). Plaintiff states no facts indicating that he had a contract with either Valeant or L'Oréal, including, for example, what consideration Plaintiff provided or promised to either

Valeant or L'Oréal in the alleged contract. *See also* section B.3 below. Plaintiff also does not state that either Valeant or L'Oréal ever indicated unequivocal assent to form a contract with him (or for that matter, that he did with either of them). Plaintiff instead alleges that he bought products from CVS Pharmacy. Without pleading a contract, he has no claim for breach of the implied covenant. *Wade*, 172 N.J. at 345 .[10]

In addition, a claim for breach of implied covenant of good faith and fair dealing should be dismissed when it does not allege any basis for breach that is different from the bases for breach of express warranty claims. *T.J. McDermott Transp. Co., Inc.. v. Cummins, Inc.*, No. CIV. 14-04209 WHW, 2015 WL 1119475, at *13 (D.N.J. Mar. 11, 2015); *Wade*, 172 N.J. at 344. Courts therefore dismiss a claim for "breach of implied covenant" if it is duplicative of breach of express warranty. *Id.* (citing *TBI Unlimited, LLC v. Clear Cut Lawn Decisions, LLC*, Civ. No. 12-3355 (RBK), 2014 WL 3853900, at *3 (D.N.J. Aug. 5, 2014)); *Dicuio*, 2012 WL 3278917 at *12; *Wade*, 172 N.J. at 344. Plaintiff's claim fails because it pleads no additional bad faith beyond the alleged mislabeling.

3. *The Unjust Enrichment Claim Should Be Dismissed Because Plaintiff Does Not Plead a Direct Relationship.*

Under New Jersey law, a claim for unjust enrichment fails where the plaintiff did not purchase directly from the defendant, because the plaintiff did not confer a benefit on defendants. *Green v. Green Mountain Coffee Roasters, Inc.*, 279 F.R.D. 275, 283 (D.N.J. 2011) ("Absent an

[10] While the New Jersey Supreme Court has held that "absence of privity between a remote supplier and an ultimate purchaser should not preclude the extension to the purchaser of the supplier's warranties . . .," it recognized that this holding was at odds with its more general jurisprudence that the UCC "generally applies to parties in privity." *Spring Motors Distributors, Inc. v. Ford Motor Co.*, 98 N.J. 555, 582, 489 A.2d 660 (1985) (describing *Santor*). The pre-UCC *Santor* and *Henningsen* cases, which extend warranty claims to parties outside privity, are thus now best understood as a product of the development of modern products liability law. *Spring Motors*, at 583 (explaining *Henningsen* and *Santor* in this fashion). These cases reflect a 1960s judicial policy decision to extend warranty coverage throughout the chain of commerce; they do not address, as *Wade* and other cases do, whether a consumer can enforce an implied covenant of good faith and fair dealing against someone who they have no contract with.

allegation of a direct relationship or a mistake, Plaintiff has insufficiently pled a claim for unjust enrichment."); *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 331 (D.N.J. 2014); *Cooper v. Samsung Elecs. Am., Inc.*, No. CIV.A. 07-3853 JLL, 2008 WL 4513924, at *10 (D.N.J. Sept. 30, 2008), aff'd, 374 Fed. App'x 250 (3d Cir. 2010) (no claim for unjust enrichment because plaintiff did not allege he purchased products directly from defendant). "When consumers purchase a product from a third party, they confer a benefit on that third party, not on the manufacturer." *Snyder v. Farnam Cos., Inc.*, 792 F. Supp. 2d 712, 724 (D.N.J. 2011) (citing cases); *Semeran v. Blackberry Corp.*, No. 2:15-CV-00750-SDW-LDW, 2016 WL 406339, at *6 (D.N.J. Feb. 2, 2016) (following *Cooper* and *Snyder*; dismissing unjust enrichment claim where plaintiff bought his Blackberry smartphone from T-Mobile and not directly from Blackberry). Here, Plaintiff alleges he bought from CVS Pharmacy, and does not allege he ever bought directly from either Valeant or L'Oréal. ECF 26 (Am. Compl.) ¶ 18. His claim for unjust enrichment should be dismissed.

4. *Plaintiff's New Jersey Consumer Fraud Act ("NJCFA") Claim Should Be Dismissed for Failure to Adequately Plead Ascertainable Loss.*

The New Jersey Consumer Fraud Act ("NJCFA") claim is inadequately pleaded. The statute requires private plaintiffs to plead and prove that they suffered an "ascertainable loss." *D'Agostino v. Maldonado*, 216 N.J. 168, 185 (2013) ("The plain language of the [NJCFA] unmistakably makes a claim of ascertainable loss a prerequisite for a private cause of action.") (citations omitted). Because "[t]he certainty implicit in the concept of an 'ascertainable' loss is that it is quantifiable or measurable," *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 248 (2005), federal district courts in New Jersey require that the "difference in value" be pleaded: "[f]ailure to quantify this difference in value results in the dismissal of a claim." *Mladenov v. Wegmans Food Mkts., Inc.*, 124 F. Supp. 3d 360, 375 (D.N.J. 2015) (quoting *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 101 (D.N.J. 2011); *Eberhart v. LG Elecs. USA, Inc.*, 188 F. Supp. 3d 401, 407 (D.N.J. 2016) ("[T]o meaningfully determine Plaintiff's ascertainable loss, Plaintiff should provide plausible facts that compare televisions that have an

increased refresh rate with televisions that have the lower refresh rate Plaintiff actually received.") (citing cases); *In re Gerber Probiotic Sales Practices Litig.*, No. CIV.A. 12-835 JLL, 2014 WL 3446667, at *2 (D.N.J. July 11, 2014) (plaintiffs' claim dismissed without prejudice where "Plaintiffs have not pleaded sufficient facts to demonstrate ascertainable loss that is quantifiable or measurable"); *Decerbo v. Melitta United States of America Inc.*, No. 8:16-CV-850-T-17AAS, 2016 WL 7206244 (M.D. Fla. Oct. 17, 2016); *Hemy v. Purdue Farms, Inc.*, No. CIV.A. 11–888 FLW, 2011 WL 6002463, at *18 (D.N.J. Nov. 30, 2011) (concluding that plaintiffs have failed to allege ascertainable loss because "they do not set out the difference in value between the promised product . . . and the actual product received").

Plaintiff here did not plead the amount he paid, or the amount that he contends he would have paid backed up with factual allegations showing why that is the amount he would have paid. His allegations are instead nearly identical to those found subject to dismissal in prior cases. *Compare* ECF 26 (Am. Compl.) ¶¶ 113-114; 51; 13 with *Mladenov v. Wegmans Food Mkts., Inc.*, 124 F. Supp. 3d 360, 374-376 (D.N.J. 2015) (holding pleading insufficient where "the Amended Complaints claim only that Plaintiffs 'would not have purchased the bread and bakery products, would not have paid as much for the products, or would have purchased alternative products in absence of Defendant's misleading advertisements"; allegation that Defendants charge a "premium" for the product, and sell other products without the labeling claim "at a substantially lower price" was also insufficient). Plaintiff's NJCFA claim should therefore be dismissed for failure to adequately plead ascertainable loss.

5. *Plaintiff's TCCWNA Claim Cannot Create a Private Right of Action To Enforce the FDCA and So Fails.*

Plaintiff's claim for violation of the New Jersey Truth In Consumer Contract Warranty and Notice Act ("TCCWNA") also fails because that statute does not create a private right of action where the underlying law, in this case the FDCA, does not.

> To properly state a claim under the TCCWNA, a plaintiff must allege each of following: (1) the plaintiff is a consumer; (2) the defendant is a seller; (3) the "seller offers a consumer contract" or gives or displays any written notice, or sign;

> and (4) the contract, notice or sign includes a provision that "violate[s] any [clearly] legal right of a consumer" or responsibility of a seller. The TCCWNA only bolsters rights established by other laws; it does not create any new consumer rights.

Mladenov v. Wegmans Food Markets, Inc., 124 F. Supp. 3d 360, 380 (D.N.J. 2015) (citations omitted).

While Plaintiff's Complaint does not identify which of his "clearly established rights" he contends Valeant or L'Oréal violated, presumably his claim is based on alleged violations of the NJCFA or the FDCA. As shown above, Plaintiff has not stated a claim under the NJCFA and it cannot therefore be the basis of a TCCWNA claim. *See Ensey v. Gov't Employers Ins. Co.*, No. CIV.A. 12–07669 JEI, 2013 WL 5963113, at *7 (D.N.J. Nov. 7, 2013) (dismissing TCCWNA claim following dismissal of NJCFA claim). To the extent Plaintiff relies on the sunscreen labeling regulations promulgated under the FDCA to establish that Valeant and L'Oréal violated his "clearly established legal rights," his claim must fail. In *Mladenov v. Wegmans Food Markets*, the court considered a TCCWNA suit against Wegman's grocery chain in which plaintiffs alleged the grocer sold bread labeled "fresh" that was in fact frozen, or otherwise not "fresh." *Mladenov*, 124 F. Supp. 3d at 366. *Mladenov* held that, to the extent the plaintiff's TCCWNA claim presupposed that an FDA regulation regarding the use of the term "fresh" in food labeling created a "clearly established legal right" that the plaintiff could enforce, his claim failed because "It is well settled . . . that the FDCA creates no private right of action." *Id.* at 380 (quoting *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999)). Likewise, Plaintiffs in this case cannot use the TCCWNA to create a private right of action to enforce 21 C.F.R. § 201.327. Plaintiff cannot "use TCCWNA to bootstrap a FDCA claim they could not otherwise bring." *Id.* (granting dismissal of TCCWNA claims). The *Mladenov* decision has also been cited with approval by the New Jersey Supreme Court. *See Dugan v. TGI Fridays, Inc.*, 231 N.J. 24, 69 (2017).

IV. CONCLUSION.

Plaintiff's claims are expressly preempted by federal law and should be dismissed with prejudice. Additionally, Plaintiff's state claims fail under New Jersey law.

Dated this 8th day of May, 2018.

By: /s/ Thomas B. Mayhew

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